SUBMISSION TO THE ACIP INQUIRY ON THE

INNOVATION PATENT - EXCLUSION OF PLANT AND

ANIMAL SUBJECT MATTER

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The Australian Centre for Intellectual Property in Agriculture (ACIPA) is a research centre based at the law schools of the Australian National University in Canberra and Griffith University in Brisbane. It commenced operations in September 2000 to undertake research in issues relating to intellectual property law, and apply that knowledge to the scientific community and industry and rural bodies. The Centre's ultimate purpose is to foster an active environment in which Australia better protects and capitalises the products of research and innovation. It has particular expertise in both patent law and plant breeder's rights.

ACIPA is keen to consider the operation of s 18 (3) and 18 (4) of the *Patents Act* 1990 (Cth), as amended by the *Patents Amendment (Innovation Patents) Act* 2000 (Cth), which stipulates that certain inventions are outside the scope of the innovation patent. S 18 (3) provides that "for the purposes of an innovation patent, plants and animals, and the biological processes for the generation of plants and animals, are not patentable inventions." However, s 18 (4) notes that "subsection (3) does not apply if the invention is a microbiological process or a product of such a process".

ACIPA submits that there are strong justifications for the exclusion of plant and animal subject matter from the scope of the innovation patent. There is currently no gap in intellectual property protection for inventions involving plant subject matter, because of the operation of the plant breeder's rights system. Animal subject matter is controversial and better left out of the scope

of the innovation patent. The innovation patent would have harmful effects upon rural and regional communities if it were to include plant and animal subject matter. It also has the potential to harm research and development in Australia in relation to plants and animals. There is a need for a comprehensive review of the operation of the innovation patent, as well as the plant breeder's scheme, before any legislative amendments are implemented.

ACIPA would like to make the following specific submissions:

1. There are still reservations about the constitutional validity of innovation patents - whereas there are no such doubts about the plant breeder's rights system.

2. The registration system for innovation patents is inferior to that demanded under the plant breeder's rights system because there is no requirement for substantive examination before the grant of rights.

3. The standard of an "innovative step" is vague and uncertain - in comparison to the requirements of distinctiveness, uniformity, and stability under plant breeder's rights.

4. The innovation patent regime fails to provide safeguards for the public interest in access to plants - unlike the plant breeder's rights system, which has a range of exceptions dealing with farmer-saved seed, among other things.

5. Patent protection of animal subject matter is controversial.

6. The innovation patent need not include plant and animal subject matter because of any international obligations.

1. Constitutional Basis of Legislation

Both innovation patents and plant breeder's rights are on the penumbra of traditional regimes of intellectual property. In the past, there have been doubts expressed about the constitutional validity of the legislation relating to such subject matter.

There are lingering reservations about the constitutional validity of the system of innovation patents. Glenn McGowan observes: "The only basis for doubt would be if the intended (as opposed to what seems to be the actual) requirements of the new amendments for innovation patentability were successful and were in fact held to be less than the inventive step required for a standard patent".[1] There might also be concerns about whether innovation patents are within the scope of "patents of innovation" under the intellectual property power of the Constitution - given that substantive examination is not required at the stage of registration. The constitutional validity of the innovation patent regime will remain uncertain until the High Court has the opportunity to review the legislation.

By contrast, the High Court of Australia has confirmed the constitutional validity of the plant breeder's rights regime. In *Grain Pool of Western Australia* v *Commonwealth*, the plaintiff, the Grain Pool of West Australia, challenged the constitutional validity of the *Plant Variety*

[1] McGowan, G. "The New Innovation Patent System: Will It Work?", *Law Institute Journal*, February 2002, p. 64-67.

Rights Act 1987 (Cth) and the *Plant Breeders' Rights Act* 1994 (Cth).[2] The defendants argued that the legislation was supported by the intellectual property power and the external affairs power of the *Constitution*.

The High Court rejected the submission of the State of Western Australia that the rights conferred by the *Plant Variety Rights Act* 1987 (Cth) and the *Plant Breeder's Rights Act* 1994 (Cth) amounted to rights "by way of positive authority to sell and export the protected variety". It held that plant variety rights and plant breeder's rights are negative rights, like those found under patent law, which give the rights-holder the power to exclude others from using the particular plant material.

The High Court held that the *Plant Variety Rights Act* 1987 (Cth) and the *Plant Breeders' Rights Act* 1994 (Cth) were valid under the intellectual property power under the Constitution. The joint judgment highlighted historical studies into the development of intellectual property. It considered the evolution of common law and statute law. It undertook a close reading of the *Plant Variety Protection Act* 1987 (Cth) and the *Plant Breeder's Rights Act* 1994 (Cth). It concluded that plant variety rights do indeed belong within the ambit of "patents of invention". The High Court found it unnecessary to consider the application of the external affairs power to the legislation.

Given this broad interpretation of the intellectual property power, it would seem that the Federal Government has the power to legislate with respect to plant breeder's rights.

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2 *Grain Pool of Western Australia* v *Commonwealth* (2000) 46 IPR 515

2. Registration

The innovation patent has replaced the petty patent as a lower tier patent to supplement the standard patent system. Essentially, this scheme offers protection for a maximum term of eight years in respect of inventions that display an innovative step. Substantive examination will only occur if directed by the Commissioner of Patents or requested by the patent owner or a third party or if there is an infringement suit.

The credibility and legitimacy of the registration system for innovation patents has come under question. Infamously, a patent attorney called John Keogh was issued with an innovation patent for a "circular transportation facilitation device".[3] He said that he patented the wheel in order to prove that the innovation patent system was flawed because it did not need to be examined by the patent office. John Keough observed: "The patent office would be required to issue a patent for anything. All they're doing is putting a rubber stamp on it ".[4] This controversy cannot be dismissed as a mere hoax. It highlights problems both with the operation of the innovation patent system, and the public perceptions of the legitimacy of the regime. As Glenn McGowan notes: "There remain problems - both conceptual and mechanical - with the new system".[5]

Daniel Stewart comments: "The innovation patent presents the potential to impose considerable costs on the innovation process, particularly the cumulative and supplementary innovation that

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[3] Cochrane, N. "Melbourne Man Patents The Wheel", The Age, 2 July 2001.

[4] *Ibid*.

[5] McGowan, G. "The New Innovation Patent System: Will It Work?", *Law Institute Journal*, February 2002, p. 64-67.

characterises much of the development in areas such as biotechnology, e-commerce and informatic databases. The lack of formal examination may lead to greater uncertainty about the validity of such patent, particularly if a different approach is to be advocated for the interpretation of standard and innovative patents with respect to questions of application".[6]

By contrast, the scheme established under the *Plant Breeder's Rights Act* 1994 (Cth) has a reputation for rigour and integrity. The scheme uses breeder testing to establish the distinctness, uniformity and stability of new varieties. The breeder or their agent carries out comparative trials, using UPOV technical guidelines, to establish that each new variety satisfies criteria of distinctiveness, uniformity and stability. To ensure technical rigour, the Plant Breeder's Rights Office requires all applicants to engage the services of an accredited qualified person. The Qualified Person, in collaboration with the Plant Breeder's Rights Office, accepts responsibility for all aspects of the comparative trial, including the choice of comparative varieties, experimental design, collection of data, statistical analysis and preparation of a description of the variety. The Plant Breeder's Rights Office publishes a description and photograph of each variety in the Plant Varieties Journal. Publication allows a breeder's peers to object to the granting of plant breeder's rights, informs industry and gives the public an opportunity to comment on individual applications.

The expansion of the innovation patent system to include plants and animal subject matter would create confusion and uncertainty amongst rural and regional communities. There would be a concern amongst plant breeders that they would need to apply for both an innovation patent

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[6] Stewart, D. "Patenting Innovations - Will it work?", Published proceedings of the Technology Transfer and Innovation 2001 Conference, Brisbane, Australia, 26-28 September 2001.

and plant breeder's rights. In "Patenting Innovations", Daniel Stewart raises concerns about the impact of innovation patents on research and development in the field of biotechnology:

> The ability to quickly and easily obtain an innovation patent will only add to the concerns over the use of patents in the biotechnology area to stifle or add costs to research and prevent the development of basic and public research. As discussed above, Innovation patents can lead to uncertainty over the protected material, patent pools, fragmentation of ownership of enabling technology, defensive patents and blocking patents. They also facilitate the imposition of reach-through licensing and extend their potential reach into the downstream markets. The modular nature of many developments in biotechnology, the importance of enabling technologies, the uncertainty over the scope of any research exception to infringement, and the potential of identified and isolated genes or gene fragments only adds to the potential of the innovation patent to impose significant costs on cumulative and subsequent research and development in this area.[7]

The accompanying increase in transaction costs would reduce the incentives for plant breeders to create new plant varieties. Furthermore innovation patents generate inherently insecure rights, and there would be uncertainties among breeders about the validity of innovation patents in infringement proceedings.

3. Threshold of Innovation

Historically, the patent system has been ill-adapted to plant varieties. Plant breeders first sought protection under the industrial patent system. However, a number of technical difficulties were encountered in seeking to apply the rules of a system designed to protect technical inventions to plant varieties, which were thought not to precisely reproduce

[7] Ibid.

themselves, and whose appearance can vary depending upon the environment in which they are grown. Margaret Llewellyn observes:

> There were two main reasons why the patent system was seen as inappropriate. First, plant material was not regarded as capable of meeting the requirements of novelty, inventive step and disclosure. Secondly, it was not thought to be in the public interest to permit such an extensive monopoly over plant varieties, given their communal importance. Underlying this was the view that it was desirable to retain, in so far as it was possible, the tradition of free exchange of new plant material between plant breeding institutes. This would ensure the widest possible dissemination and use of the new combinations of genetic information.[8]

For these reasons, it was decided to introduce a special form of protection which would be designed to support a specific industry, the plant variety right.

The innovation patent can be used to protect inventions that are incremental, or small advances to devices, substances, methods or processes, that display an "innovative step". S 7 (4) of the *Patents Act* 1990 (Cth) provides that “an invention is to be taken to involve an innovative step when compared with the prior art base unless the invention would, to a person skilled in the relevant art, in the light of the common general knowledge as it existed in the patent area before the priority date of the relevant claim, only vary from the kinds of information set out in subsection (5) in ways that make no substantial contribution to the working of the invention”.

The invention must also satisfy the other criteria for a valid standard patent, such as being "new", "useful", and a "manner of manufacture". S 18 (1A) of the *Patents Act* 1990 (Cth)

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[8] Llewelyn, M. "The Legal Protection Of Biotechnological Inventions: An Alternative Approach", *European Intellectual Property Review*, 1997, Vol. 19 (3), p. 115.

provides that “an invention is a patentable invention for the purposes of an innovation patent if the invention, so far as claimed in any claim: (a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; (b) when compared with the prior art base as it existed before the priority date of the claim: (i) is novel; and (ii) involves an inventive step; and (c) is useful; and (d) was not secretly used in the patent area before the priority date of that claim by on or behalf of, or with the authority of, the patentee or nominated person or patentee’s or nominated person’s predecessor to the title."

However, there are problems with the definition and interpretation of an "innovative step". Glenn McGowan comments:

> There is real doubt about whether the new legislation actually does impose or require the lower level of invention that was intended... It seems on any reasonable view that the new s 7 (4) either adds nothing (because what it adds is less than that required for an invention the subject of the standard patent) or adds something, in which case the height of the hurdle for obtaining a patent has been raised.[9]

Similarly, Daniel Stewart is concerned as to how the standard of an "innovate step" will interact the requirement of "novelty": "It is open to question to what extent this will go beyond the novelty test as applied in the case of a standard patent".[10] He adds: "Of more concern is the extent to which an innovative step will constitute a significant requirement".[11] Courts may struggle in making fine distinctions between an "innovative step", and the threshold

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[9] McGowan, G. "The New Innovation Patent System: Will It Work?", *Law Institute Journal*, February 2002, p. 64-67.

[10] Stewart, D. "Patenting Innovations - Will it work?", Published proceedings of the Technology Transfer and Innovation 2001 Conference, Brisbane, Australia, 26-28 September 2001.

[11] *Ibid*.

requirement of inventiveness, the need for novelty, as well as the standard of an innovative step.

Much will depend on the first test case of the innovation patent.[12] DataDot Technology has launched legal action in the Federal Court, claiming that a rival company, Alpha Microtech, has infringed its innovation patent. DataDot has developed an invention which sprays cars with more than 10,000 'micro-dots' to deter car thieves from breaking up stolen cars to rebuild them or sell their parts. Alpha is offering a similar system, called the SmartDot security marking and identification system. The pending Federal Court judgment may give a better idea of the operation of the innovation patent system.

Nonetheless there is still concern as to how this vague standard of an "innovative step" would be applied to plant and animal subject matter. IP Australia have released guidelines in respect of obtaining standard patents for plants.[13] It advises that the range of patentable subject matter for plants. A plant variety is patentable under the *Patents Act* 1990 (Cth) if it meets the standard requirements for patentability. Furthermore, a patent application in respect of a plant variety must be capable of written description. It must be replicable based on a written description provided in a patent specification. Full description of the plant or plant variety means an inclusion of the full morphological, biochemical and taxonomic characteristics of the organism known to the applicant. It also includes a full description of any scientific testing characteristics if available. There must be sufficient clear information to enable the specialist to fill in any missing gaps in the description of the invention without conducting lots of experimentation or resorting to invention to discover the conditions necessary for the work.

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12 Kitney, D. "News - First Test Of Innovation Patent Status", *Australian Financial Review*, 5 August 2002.

13 IP Australia. "Australian Patents For Plants", November 1998.

However, such requirements are a little vague as compared to the standards necessary for plant varieties under the *Plant Breeder's Rights Act* 1994 (Cth).

The issues paper displays a poor understanding of the requirements of the *Plant Breeder's Rights Act* 1994 (Cth). S 43 (1) provides that "a plant variety in which an application for PBR is made registrable if the variety has a breeder, and the variety is distinctive, uniform, stable, and has not been exploited. First there is a need to identify the breeder for the purposes of the plant breeder's rights. Second, a plant variety must be distinct in order to be registrable.[14] A plant variety is distinct if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge.[15] Third, a plant variety is uniform if, subject to the variation that may be expected from the particular features of its propagation, it is uniform in its relevant characteristics on propagation.[16] The required standard of uniformity for each type of propagation is set out under the UPOV technical guidelines. Fourth, the plant variety is stable if its relevant characteristics remain unchanged after repeated propagation or reproduction.[17] Breeders of varieties propagated from seed need to demonstrate stability by including two generations in the comparative trial. Finally, the plant variety must not have been exploited, or recently exploited.[18]

There are further requirements that might need to be satisfied in respect of essential derivation. A plant variety is taken to be an essentially derived variety of another plant variety if it is

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14 S 43 (1) of the *Plant Breeder's Rights Act* 1994 (Cth)

15 S 43 (2) of the *Plant Breeder's Rights Act* 1994 (Cth)

16 S 43 (3) of the *Plant Breeder's Rights Act* 1994 (Cth)

17 S 43 (4) of the *Plant Breeder's Rights Act* 1994 (Cth)

18 *Sun World International Inc* v *Registrar of Plant Breeder's Rights* 1998

predominantly derived from that other plant variety; and retains the essential characteristics that result from the genotype; and it does not exhibit any important (as distinct from cosmetic) features that differentiate it from that other variety.[19] The criteria of essential derivation plays an important role in mediating between first breeders and later breeders. It also leaves space open for the operation of standard patents in respect of biotechnological inventions.

One possible flow-on consequence of changing the scope of the innovation patent would be a reconsideration of the criteria of essential derivation. Conceivably, the Plant Breeder's Rights Office could relax the criteria of essential derivation in order to increase the scope of possible applications for plant breeder's rights.[20] In so doing, there would be a much greater incentive for researchers in the field of biotechnology to obtain protection under plant breeder's rights than the much more expensive system of standard patents.

4. Exceptions

There is a dearth of defences in respect of patent infringement of both innovation patents and standard patents. First of all, there is no defence to patent infringement in respect of experimental use in the context of Australia. Thus plant breeders engaging in experimental research might be exposed to claims of patent infringement. Second, there is no special provision for agricultural products under the *Patents Act* 1990 (Cth). Thus saving farm seed could amount to patent infringement. Third, there is no scheme for equitable remuneration under the *Patents Act* 1990 (Cth). This may impede the development of end-point royalties in

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19 S 4 of the *Plant Breeder's Rights Act* 1994 (Cth)

20 Draft Report of the Expert Panel on Breeding. "Clarification Of Plant Breeding Issues Under the Plant Breeder's Rights Act 1994 (Cth)". February 2002.

the context of the grains industry. Fourth, the compulsory licensing provisions under the *Patents Act* 1990 (Cth) are long, complex, and unwieldy.[21] As a result, they have laid largely dormant. It is therefore unlikely that they would be of use to rural and regional communities. Finally, the court can refuse to withhold remedies in cases of innocent infringement.[22] However, the circumstances in which they can exercise such a discretion are limited.

The case of *Monsanto* v *Percy Schmeiser* illustrates some of the limitations of the patent system in dealing with agricultural biotechnology.[23] Monsanto brought an action for patent infringement against Percy Schmeiser, a 70 year old farmer from Saskatchewan Canada. He had grown canola since the 1950's. Monsanto claimed that in 1998 the defendants planted glyphosate-resistant seeds to grow a crop of canola, for harvest, having a gene or cell that is the subject of the plaintiff's patent. Justice McKay held that the growing and sale of Roundup tolerant canola by the defendants infringed the exclusive rights of the plaintiffs to use the patented gene and cell. His Honour found it immaterial that Percy Schmeiser was a passive infringer. Commenting upon the case, Professor Brad Sherman said that patent law must have stronger defences built into it, like the farmer's privilege in plant breeder's rights.[24] He said it was necessary to shift the balance between patent owners and patent users.

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21 S 133 of the *Patent Act* 1990 (Cth)

22 S 123 of the *Patent Act* 1990 (Cth)

23 *Monsanto* v *Percy Schmeiser* (2001) FCT 256

24 Sherman, B. *Biological Inventions and the Problem of Passive Infringement, Australian Intellectual Property Journal*, August 2002, Vol. 13 (3), p. 146. See also Lee, M. and Burrell, R. "Liability For The Escape Of GM Seeds: Pursuing The 'Victim'?", *The Modern Law Review*, 2002, Vol. 65, p. 517.

In contrast to the patent system, the *Plant Breeder's Rights Act* 1994 (Cth) provides a number of exceptions to ensure that there is reasonable public access to new varieties of plants. There is a much better balance between the interests of owners and users under this regime. First, certain acts done for private, experimental or breeding purposes do not infringe plant breeder's rights.[25] Second, the conditioning and use of farm saved seed does not infringe plant breeder's rights.[26] Third, the *Plant Breeder's Rights Amendment Bill* 2002 (Cth) plans to introduce new provisions dealing with equitable remuneration. This legislative amendment is intended to provide legal backing for the scheme of end point royalties. Fourth, "the grantee of PBR in a plant variety must take all reasonable steps to ensure reasonable public access to that plant variety."[27] The Secretary of the Department of Agriculture, Fisheries and Forestry Australia has the power to provide a compulsory license in the appropriate circumstances.[28] Finally, the Federal Court may refuse to award damages, or make an order for an account of profits, if the person satisfies the court that, at the time of the infringement, the person was not aware of, and had no reasonable grounds for suspecting the existence of that right.[29] Such public interest exemptions under plant breeder's rights will be undermined if the scope of the innovation patent is expanded to include plant material.

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[25] S 16 of the *Plant Breeder's Rights Act* 1994 (Cth)

[26] S 17 (1) of the *Plant Breeder's Rights Act* 1994 (Cth); and *Asgrow Seed Company* v *Winterboer et al* (1995) 513 US 179.

[27] S 19 (1) of the *Plant Breeder's Rights Act* 1994 (Cth)

[28] The case of *Sacker Potatoes Ltd* v *C Meijer BV* (Unreported, October 31, 2001) considered whether compulsory exploitation rights should be granted in protected variety of potato on grounds that refusal to issue licence was unreasonable and right holder was failing to satisfy demand in UK market.

[29] S 57 (1) of the *Plant Breeder's Rights Act* 1994 (Cth)

Plant breeders may act under the belief that their conduct is permissible under the *Plant Breeder's Rights Act* 1994 (Cth) - only to discover that they might nonetheless be infringing an innovation patent. This lack of consistency between plant breeder's rights and innovation patents will give rise to uncertainty, confusion, and misunderstanding amongst rural and regional communities.

Furthermore, it should be noted that the *Plant Breeder's Rights Act* 1994 (Cth) is currently subject to the full force of the competition provisions of the *Trade Practices Act* 1974 (Cth). It therefore is much more sensitive to competition policy than the patent system. The sui generis system is not mentioned at present in s 51 (3) of the *Trade Practices Act* 1974 (Cth), which limits the range of competition actions that can be brought with respect of intellectual property. However, the Federal Government has expressed a desire to include plant breeder's rights in this regime in the future.

5. Animal Subject Matter

The protection of animal subject matter under patent law has been controversial. There should be reservations as to whether animal breeding should come within the scope of innovation patents.

Most notably, there has been ongoing litigation over the transgenic animal, OncoMouse. in the European Union.[30] The following account derives from a recent press release from the European Patent Office (EPO).

[30] EPO press release. "'Oncomouse' opposition proceedings resume at EPO", November 2001, http://www.european-patent-office.org/news/pressrel/2001_11_05_e.htm

The "oncomouse" application was filed with the EPO in June 1985. Initially, on 14 July 1989, the examining division refused the application, inter alia on the grounds that Article 53 (b) of the European Patent Convention prohibits European patents on animals per se. The applicant appealed against that decision, and on 22 October 1990 an EPO technical board of appeal set it aside and sent the case back for re-examination.

The board of appeal held that Article 53(b) EPC rules out patents on animal varieties, not animals generally. The examiners therefore had to decide whether the application was for an "animal variety" within the meaning of the provision, and also whether to invoke Article 53 (a) EPC which prohibits patents for "inventions the publication or exploitation of which would be contrary to ordre public or morality".

In a second decision in October 1991, the examining division granted the "oncomouse" patent as complying with the EPC, commenting that the patent application's purpose - to facilitate cancer research and prevention - was of such importance for humanity as to outweigh any disadvantages such as the suffering of the animals concerned.

In 2001, The European Patent Office has resumed opposition proceedings against Harvard University's "oncomouse" patent.[31] The opposition division in Munich has invited the parties - Harvard University as the patent proprietor and 16 different groups, individuals, political parties and organisations wanting the patent revoked - to three days of oral proceedings.

[31] Ibid

In light of this controversy, it would be inappropriate to expand the scope of innovation patents to include animal subject matter. Past experience has shown that there is a need for stringent examination and re-examination of animal subject matter - as well as the scope for complex opposition proceedings. The innovation patent regime would be a poor framework for animal subject matter - especially given the concerns about the lack of substantive examination at the stage of registration.

6. International Context

Finally, it should be stressed that the innovation patent need not include plant and animal subject matter because of any international obligations or norms. It must also be recognised that there is no consensus as to whether second tier patent protection is appropriate - let alone as to what model for such a system would be ideal.

Some commentators have argued that Australia should lift the restrictions on animal and plant subject matter in light of international practice. Notably, Des Ryan argues:

> The Agreement on Trade Related Aspects of Intellectual Property provides by Article 27 (3) that member states may exclude from patentability, plants, animals and other micro-organisms and essentially biological processes for their production. The European Patent Convention contains a provision to that effect. In its negotiations and discussions, until recently, Australia has taken a position in favour of the restriction or elimination of this possibility of this exclusion from Article 27 (3) of the TRIPs Agreement. The position was taken, I believe, principally on the basis that Australia does rather better in the biological and medical sciences than it does in other areas, and notwithstanding such subterfuges as the "Swiss

type" claim, Australian industries had been disadvantaged by the exclusion from the European patent particularly, in the field of plant biology.[32]

However, it is a mistake to confuse a negotiating position with international obligations. The World Trade Organization negotiations at Doha in 2001 have not resolved whether there should be a revision of Article 27 (3) of the TRIPS Agreement. Furthermore it is also misleading to there is no protection for plant subject matter in the European Union in the absence of patent protection. Obviously this overlooks the important role played by plant breeder's rights.

The European Union provides under the Biotechnology Directive that a patent shall not be granted for "any variety of animal or plant or any essentially biological process for the production of animals or plants, not a being a microbiological process or other technical process or the product of such a process". The first form of subject matter excluded from protection are "animal varieties". The meaning of "animal varieties" has been considered in the OncoMouse decision. The second form of biological subject matter that is excluded from the scope of protection is "plant varieties". Lionel Bently and Brad Sherman comment in Intellectual Property Law: "In order to ensure that plant breeders were not able to obtain patent protection *and* plant variety protection, it was decided that the two conventions should be mutually exclusive: a person could be given either a *sui generis* plant breeder's right or patent protection, but not both".[33] The Enlarged Board of Appeal of the European Patent Office affirmed in the *Novartis* decision that the extent of the exclusion for plants is the obverse of

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[32] Ryan, D. "Innovation Patents - What Is There Likely Impact?", *Intellectual Property Forum*, March 2002, Issue 48, p 30.

[33] Bently, L. and Sherman, B. *Intellectual Property Law*. Oxford: Oxford University Press, 2001, p. 396.

the availability of plant variety rights and that plant varieties are only granted for specific plant varieties.[34]

The United States of America is unique because it had established a system of plant patents prior to the implementation of a legislative regime for plant varieties. It can therefore be distinguished from the situation of Australia. In *JEM Ag Supply Inc* v *Pioneer Hi-Bred International Inc*, the United States Supreme Court found that newly developed plant breeds can receive utility patents - as well as plant breeder's rights and plant patents.[35] This case is only of academic interest. It certainly cannot be used to support the expansion of the innovation patent system in the context of Australia.

Given this international context, there is no need for Australia to expand the scope of the innovation patent to include animal and plant subject matter because of international obligations or the practice of other national jurisdictions. Furthermore there is no demand for Australia to change its laws out of a desire for harmonisation. Quite clearly, there is no international norm as to the appropriate interaction between plant breeder's rights and patent law - especially given the wide divergence in the approaches of the European Union and the United States of America.

Moreover, it should be noted that there is not even any international consensus regarding second tier patent protection. A *Harvard International Journal* article on "Second Tier Patent Protection" conducts an international survey of second tier patent proposals in Europe,

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[34] *Novartis/ Transgenic Plant* (T1054/96) [1999] EPOR 123

[35] *JEM Ag Supply Inc* v *Pioneer Hi-Bred International Inc* (2001) 534 US 124

Australia, and the United States.[36] Mark Janis comments that "modern second tier patent proposals, including both the European and Australian initiatives, are ill-considered, and that Europe, Australia, and the United States would all be better served by directing energies towards the reform of regular patent law, and towards the exploration of alternative avenues for protecting incremental innovation".[37]

Conclusion

ACIPA submits that there are strong justifications for the exclusion of plant and animal subject matter from the scope of the innovation patent. It maintains that such subject matter is much better accommodated under the plant breeder's rights system.

At the outset, ACIPA first notes that there have been doubts raised about the constitutional validity of both innovation patents. By contrast, the High Court has confirmed that the plant breeder's rights system is a valid exercise of legislative power.

Second, ACIPA observes that there are manifold problems with the registration of innovation patents - in particular, with the lack of substantive examination. It maintains that the system of plant breeder's rights has much more legitimacy and credibility. Third, ACIPA comments that the standard of an "innovative step" will create confusion and uncertainty in respect of plant subject matter. The standards of distinctiveness, uniformity, and stability under the plant breeder's rights regime are much better adapted to the needs of plant breeders. Fourth, ACIPA observes that the innovation patent regime will have a deleterious impact upon regional and

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36 Janis, M. "Second Tier Patent Protection", *Harvard International Law Journal*, 1999, Vol. 40, p. 151.

37 Ibid.

rural communities. It maintains that the plant breeder's rights regime has a much better balance through the range of exceptions and exemptions.

Fifth, ACIPA comments upon the controversy that has attended patent protection of animal subject matter. In such circumstances, it would be sensible to exclude animal subject matter from the scope of the innovation patent. Sixth, ACIPA notes that Australia is not compelled to provide concurrent protection of plant and animal subject matter under its international obligations. It observes that the exclusion of such subject matter from the scope of innovation patents is in step with international practice.

In conclusion, ACIPA questions the wisdom of conducting an ad hoc review of the exclusion of plant and animal subject matter from the scope of the innovation patent, so soon after the legislative process has finished. In his second reading speech, the Honourable Warren Entsch observed:

> Although innovation patents will be available for most of the types of invention currently covered by standard patents, they will not be available for plants and animals, or biological processes for the generation of plants and animals. This exclusion does not include microbiological processes and innovation patents will be available for processes such as cheese and wine making and the synthesis of industrial compounds using micro-organisms.[38]

[38] Entsch, Warren, MP (Leichhardt, Parliamentary Secretary to the Minister for Industry, Science and Resources, LP, Government). "Second Reading Speech on the Patents Amendment (Innovation Patent) Bill 2000 (Cth)", House Hansard, 29 June 2000, p. 18583.

It would be premature to revisit the legislative compromises and the political decisions that took place in respect of the *Patent Amendment (Innovation Patent) Act* 2000 (Cth), and second guess the will of Parliament on this topic. ACIPA advises that a comprehensive review of the innovation patent system is necessary after an appropriate period of time has elapsed. A proper review of all aspects of the new registration system should be conducted - rather than an examination of a single issue in isolation.

SUPPLEMENTARY SUBMISSION TO THE ACIP INQUIRY INTO THE INNOVATION PATENT - EXCLUSION OF PLANT AND ANIMAL SUBJECT MATTER

MATTHEW RIMMER

The Australian Centre for Intellectual Property in Agriculture (ACIPA) is a research centre based at the law schools of the Australian National University in Canberra and Griffith University in Brisbane. It commenced operations in September 2000 to undertake research in issues relating to intellectual property law, and apply that knowledge to the scientific community and industry and rural bodies. The Centre's ultimate purpose is to foster an active environment in which Australia better protects and capitalises the products of research and innovation. It has particular expertise in both patent law and plant breeder's rights.

ACIPA made an initial submission to the Advisory Council on Intellectual Property in relation to the "innovation patent - exclusion of plant and animal subject matter". It also participated in the round-table discussion at Stamford Plaza on the 18 June 2003. ACIPA welcomes the opportunity to make a supplementary submission to the Advisory Council on Intellectual Property in respect of the "innovation patent - exclusion of plant and animal subject matter". It has ten main points.

1. ACIPA supports the submission of AFFA that the initial issues paper and the roundtable discussion provided an inadequate basis for a consideration of the exclusion of plant and animal subject matter from the innovation patent. The discussion of plant breeders rights was notably poor. In particular, it was a concern that there was no cost/ benefit analysis of the proposed changes to the law in line with the competition policy of the Government.

2. ACIPA advises that a comprehensive review of the innovation patent system is necessary after a suitable period of time has elapsed. In particular, a number of deficiencies in the regime need to be addressed - including the lack of substantive examination, the vagueness of an innovative step, and the paucity of defences.

3. ACIPA comments that the discussion over the innovation patent, and the exclusion of plant and animal subject matter, needs to be better co-ordinated with the larger Australian Law Reform Commission inquiry into gene patenting.

4. ACIPA notes that there was widespread industry dissatisfaction in the submissions and the round-table discussion with the registration system for the innovation patent. The empirical evidence suggested that only 10 per cent of innovation patents were being substantively examined - whether by the instigation of the applicant or the commissioner of the patents. Such a low rate of substantive examination devalues the system of innovation patents as a vehicle for commercialisation and investment.

5. ACIPA acknowledges the concern expressed in the submissions and at the roundtable discussion that the threshold of an "innovative step" for an innovation patent was vague and uncertain. It notes the evidence of the registrar of the Plant Breeders' Rights Office that the majority of applications for plant breeders' rights would also satisfy the requirements for an innovation patent. ACIPA observes that this would result in a clear-cut conflict between the two regimes. It also casts doubt on the Advisory Council's schematic representation of plant breeders' rights, innovation patents, and standard patents as a tiered, hierarchal order.

6. ACIPA has grave concerns that the extension of the innovation patent to include plant subject matter would jeopardise a number of important defences under plant breeders' rights - most notably, farm-saved seed. Conflicts already exist in relation to the interaction between standard patents and plant breeders' rights. ACIPA also expresses doubts about the legality of using private contracts and terminator technologies to oust defences under plant breeders' rights. It is important that the Advisory Council on Intellectual Property recognise the political support for such defences amongst rural and regional constituencies of the Federal Government.

7. ACIPA comments that there is no universal acceptance of a second-tier patent system. As a result, it would be very difficult to commercialise innovation patents in other jurisdictions. ACIPA recommends that the plant breeders' rights system is a much better system for the commercialisation of plant innovations because of the international framework established under the UPOV convention.

8. ACIPA concludes that the plant breeders' rights regime is the most appropriate legal regime to deal with plant innovations. It recommends that the innovation patent should continue to exclude plant subject matter, especially in light of the dearth of empirical evidence or industry support for its inclusion.

9. ACIPA supports the submission of the Australian Institute of Marine Sciences that the inclusion of microbiological processes within the scope of the innovation patent is problematic.

10. ACIPA notes that industry specific conventions exist for animal breeding. The extension of the innovation patent to animal breeding could cause great concern amongst a number industries - such as kennel clubs, horse racing, and livestock producers. ACIPA

supports the submission of AFFA that there is no industry support for the extension of the innovation patent to animal breeding.